REMARKS

Applicants are amending this application to cancel claims 1 to 9 and to add new claims 38 to 52. Basis for new claims 38 to 52 is found, for example, in claims 20-36 as originally filed, in the specification on page 3, line 15 to page 4, line 6, and on page 4, line 32 to page 5, line 24, and on page 11, lines 19-25.

CLAIM REJECTION – 35 U.S.C.§112, second paragraph

Claims 1-9 stand rejected under 35 U.S.C.§112, second paragraph.

Applicants are amending this application by canceling claims 1-9 and thereby make this ground of rejection moot.

Applicants assert that newly added claims 32-42 are in statutory compliance with all aspects of 35 U.S.C.§112, including §112 second paragraph.

CLAIM REJECTION – 35 U.S.C.§102(e)/ 35 U.S.C .§103(a)

Claims 1-9 stand rejected under 35 U.S.C.§102(a) as being anticipated by or in the alternative under 35 U.S.C.§103(e) as being obvious over U.S. Patent No. 6,172,046

Applicants are amending this application by canceling claims 1-9 and thereby make this ground of rejection moot.

New claims 38 to 52 are directed to a method of treating a patient with chronic hepatitis C infection to eradicate detectable HCV-RNA by quantitative- PCR ("qPCR") by administering to such a patient specific amounts of ribavirin and of pegylated interferon-alfa-2b during two treatment periods of specified duration. The lower limit of detection of HCV-RNA by qPCR is 100 copies/mL (See specification page 11, lines 19-25).

Neither U.S. Patent No. 6,172,046 or newly cited U.S. Patent No. 6,472,373 disclose use of two treatment periods of specified duration with specific amounts of ribavirin and of pegylated interferon alfa-2b administered in each.

Applicants also assert that neither U.S. Patent makes the claimed invention, as amended, obvious under 35 USC§103(a).

Applicants point out that terminal disclaimers for U.S. Patent Nos. 6,172,046 and for U.S. Patent Application Serial No. 09/311,487, now U.S. Patent No. 6,472,373 were enclosed with the Amendment, dated December 14, 2001, and filed in the U.S.P.T.O. on January 11, 2002.

Reconsideration and withdrawal of this ground of rejection are urged.

If Applicants can be of any assistance in advancing prosecution, please call the undersigned attorney of record.

Respectfully submitted,
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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231, on

January 30, 2003

Thomas D. Hoffman
Registered Representative

Signature

1/30/2003
Date

APPENDIX I

New Claims

Please cancel claims 1-9 and add the following new claims 38-52:

38. A method of treating a patient having a chronic hepatitis C infection to eradicate detectable HCV-RNA as measured by quantitative PCR ("qPCR") which comprises (1) administering to the patient in a first treatment time period of about at least about four weeks up to about twelve weeks, about 400-1600 mg per day of ribavirin and about 1.5 micrograms per kilogram of pegylated interferon-alfa-2b twice a week, followed by (2) administering to the patient in a second treatment time period of about up to about forty-four weeks, about 800-1200 mg per day of ribavirin and about 0.5 to about1.5 kilogram per micrograms of pegylated interferon-alfa-2b once a week, wherein the patient has no detectable HCV-RNA as measured by qPCR at the end of the second treatment time period and no detectable HCV-RNA as measured by qPCR for at least 24 weeks after the end of the second treatment time period.

39. The method of claim 38, wherein the amount of ribavirin administered in the first treatment time period is from 600 to 1600 mg per day.

40. The method of claim 38, wherein the amount of ribavirin administered in the second treatment time period is from 1000 to 1600 mg per day.

41. The method of claim 38, wherein the first treatment time period is four weeks and the second period is forty-four weeks.

42. The method of claim 38, wherein the amount of pegylated interferon alfa-2b administered in second treatment time period is 1.5 micrograms/kilogram once a week.

43. The method of claim 38, wherein the amount of ribavirin administered in the first and second treatment time periods is from about 800 to 1200 mg per day.

44. The method of claim 38 wherein the amount of ribavirin administered in the first and second treatment time period is about 1000 to 1200 mg/kg per day.

45. A method of treating a patient having a chronic hepatitis C infection to eradicate detectable HCV-RNA as measured by qPCR which comprises (1) administering to the patient, in a first treatment time period week of about four weeks, about 400-1600 mg per day of ribavirin and 1.5 micrograms per kilogram of pegylated interferon-alfa-2b twice a week, followed by (2) administering to the patient, in a second treatment time period of about forty-four weeks, about 800-1200 mg per day of ribavirin and about 0.5 to 1.5 micrograms per kilogram of pegylated interferon-alfa-2b once a week wherein the patient has no detectable HCV-RNA as measured by qPCR at the end of the second treatment time period and no detectable HCV-RNA as measured by qPCR for at least 24 weeks after the end of the second treatment time period.

46. The method of claim 45, wherein the amount of ribavirin administered in the first treatment time period is from 600 to 1600 mg per day.

47. The method of claim 45, wherein the amount of ribavirin administered in the second treatment time period is from 1000 to 1600 mg per day.

48. The method of claim 45, wherein the amount of ribavirin administered in the first and second treatment time periods is from about 800 to 1200 mg per day.

49. The method of claim 45 wherein the patient having chronic hepatitis C infection is a naive patient having HCV genotype 1, 2 or 3.

50. The method of claim 45, wherein the amount of pegylated interferon alfa-2b administered in second time period is 1.5 micrograms/kilogram once a week.

51. The method of claim 45, wherein the amount of pegylated interferon alfa-2b administered in second time period is 1.0 micrograms/kilogram once a week.

52. The method of claim 45, wherein the amount of pegylated interferon alfa-2b administered in second time period is 0.5 micrograms/kilogram once a week.